Component Analysis

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- Component analysis is the individual assessment of benefit (prospect of direct benefit or no prospect of direct benefit) and risk (minimal risk or above minimal risk) of each intervention or procedure in a study.
- Drs. Nelson and Levine will provide a detailed overview of the historical, ethical and regulatory aspects.

The Issue

- Many ethicists support the application of component analysis in IRB review of research with children (and other vulnerable populations).
- SACHRP has recommended that OHRP require the application of component analysis in IRB review of research with children.

The Issue

- The FDA Office of Pediatric Therapeutics recommends the application of component analysis in IRB review of research with children.

The Problem

- Component analysis is poorly defined, the literature is simultaneously sparse and complicated, and the regulatory status is not clear.
- The early literature consists of work by the National Commission in the 1970s and then work by NBAC in 2000 and 2001.

The Problem

- The early literature is dense, does not easily lend itself to training IRB members and investigators, and was written before FDA adopted Subpart D, “Additional Safeguards for Children in Clinical Investigations.”
- The NBAC work recommends that Subpart D be drastically revised.

The Problem

- The literature from 2001 forward is limited in detail, usually refers back to the NBAC work, and often is part of a broader debate on clinical equipoise.
- As such, it is of limited value in training IRB members and investigators.

Ideal Outcome

- Holy Grail – a joint FDA/OHRP guidance explaining that component analysis is an integral part of the application of Subpart D (a “must” rather than a “should”) and providing detail regarding application and documentation in IRB minutes.
- Doesn’t have to use the term “component analysis,” could just describe how to interpret and apply Subpart D.

Other Outcomes in Order of Desirability

- Separate guidances from either or both FDA and OHRP.
- Another SACHRP recommendation supplying greater detail about application and documentation.
- Stimulation of an article or other training source that can be readily accessed and used for IRB and investigator training purposes.